

businesses or other for-profit institutions or groups.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	120	1	120	12	1,440

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 6, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning and Legislation.*

[FR Doc. 99-20794 Filed 8-11-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99N-0926]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Regulations Under the Federal Import Milk Act; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 26, 1999 (64 FR 40379). The document announced an opportunity for public comment on a collection of information that had been submitted to the Office of Management and Budget for review and clearance.

**DATES:** August 12, 1999.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 99-18927, appearing on page 40379 in the **Federal Register** of Monday, July 26, 1999, the following correction is made:

1. On page 40379, in the third column, in the first full paragraph, beginning in the fourth line, "No comments were received." is corrected to read "One comment was received that was supportive of the Federal Import Milk Act and encouraged FDA to continue this information collection request."

Dated: August 5, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning and Legislation.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99N-1010]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Investigational New Drug Regulations**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Submit written comments on the collection of information by September 13, 1999.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

## Investigational New Drug (IND) Regulations—21 CFR Part 312 (OMB Control Number 0910-0014)—Renewal

FDA is requesting OMB approval for the reporting and recordkeeping requirements contained in FDA's regulation "Investigational New Drug Application" part 312 (21 CFR part 312). This regulation implements provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) to issue regulations under which the clinical investigation of the safety and effectiveness of unapproved new drugs and biological products can be conducted.

FDA is charged with implementing statutory requirements that drug products marketed in the United States be shown to be safe and effective, properly manufactured, and properly labeled for their intended uses. Section 505(a) of the act provides that a new drug may not be introduced or delivered for introduction into interstate commerce in the United States unless FDA has previously approved a new drug application (NDA). FDA approves an NDA only if the sponsor of the application first demonstrates that the drug is safe and effective for the conditions prescribed, recommended, or suggested in the product's labeling. Proof must consist, in part, of adequate and well-controlled studies, including studies in humans, that are conducted by qualified experts. The IND regulations establish reporting requirements that include an initial application as well as amendments to that application, reports on significant revisions of clinical investigation plans, and information on a drug's safety or effectiveness. In addition, the sponsor is required to give FDA an annual summary of the previous year's clinical experience. Submissions are reviewed by medical officers and other agency scientific reviewers assigned responsibility for overseeing the specific study. The IND regulations also contain recordkeeping requirements that pertain to the responsibilities of sponsors and investigators. The detail and complexity of these requirements are dictated by the